UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION

Mara Schwartz, Plaintiff, vs. Medtronic MiniMed, Inc., MiniMed Distribution Corp., Medtronic, Inc., Medtronic USA, Inc., Becton Dickinson and Company & John Doe Defendants 1-5 Defendants.	)	Civil No. 8:20-cv-00804-BHH **DEFENDANTS MEDTRONIC MINIMED, INC., MINIMED DISTRIBUTION CORP., MEDTRONIC, INC., AND MEDTRONIC USA, INC.'S ANSWER TO PLAINTIFF'S COMPLAINT, AFFIRMATIVE DEFENSES, AND DEMAND FOR BIFURCATED TRIAL** **JURY TRIAL DEMANDED**

Defendants Medtronic MiniMed, Inc., MiniMed Distribution Corp., Medtronic, Inc., and Medtronic USA, Inc., (collectively "Medtronic"), by and through their undersigned counsel, file their Answer and Affirmative Defenses to Plaintiff's Complaint and Jury Demand ("Complaint"), deny each and every allegation, statement, matter, and thing contained in the Complaint, except as expressly admitted, qualifiedly admitted, alleged, or explained, and further respond to the Complaint's specific numbered and unnumbered paragraphs as follows:

JURISDICTION AND VENUE[1]

1. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint.

2. In response to Paragraph 2 of the Complaint, Medtronic admits that Medtronic MiniMed, Inc. is a corporation organized under the laws of the State of Delaware with its

[1] Medtronic includes the headings and subheadings from Plaintiff's Complaint merely for convenience. Medtronic denies any averments contained in the Complaint's headings and subheadings.

principal place of business located at 18000 Devonshire Street, Northridge, California, 91325. Medtronic also admits that Medtronic MiniMed, Inc. conducts business in South Carolina. Medtronic denies that CT Corporation System is Medtronic MiniMed, Inc.'s registered agent or that Medtronic MiniMed, Inc. may be served with process at 818 West 7th Street, Los Angeles, California, 90017. The remaining averments in Paragraph 2 of the Complaint contain legal conclusions to which no response is required.

3. In response to Paragraph 3 of the Complaint, Medtronic admits that MiniMed Distribution Corp. is a corporation organized under the laws of the State of Delaware with its principal place of business located at 18000 Devonshire Street, Northridge, California 91325. Medtronic also admits that MiniMed Distribution Corp. conducts business in South Carolina. Medtronic further admits that MiniMed Distribution Corp. has an agent of record, Corporation Service Company, Inc., at 1703 Laurel Street, Columbia, South Carolina, 29201. The remaining averments in Paragraph 3 of the Complaint contain legal conclusions to which no response is required.

4. In response to the averments of Paragraph 4 of the Complaint, Medtronic admits that Medtronic, Inc. is a corporation organized under the laws of the State of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota, 55432. Medtronic also admits that Medtronic, Inc. conducts business in South Carolina. However, Medtronic further states that Medtronic, Inc. is not a proper party to this action because it is not involved in the design, manufacture, marketing, distribution, testing and/or sale of the diabetes products at issue. Medtronic further admits that Medtronic, Inc. has an agent of record, Corporation Service Company, Inc., at 1703 Laurel Street, Columbia, South Carolina, 29201. The remaining averments in Paragraph 4 of the Complaint contain legal conclusions to which no response is required.

5. In response to the averments in Paragraph of the Complaint, Medtronic admits that Medtronic USA, Inc. is a corporation organized under the laws of the State of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota, 55432. Medtronic also admits that Medtronic USA, Inc. conducts business in South Carolina. However, Medtronic further states that Medtronic USA, Inc. is not a proper party to this action because it is not involved in the design, manufacture, marketing, distribution, testing and/or sale of the diabetes products at issue. Medtronic further admits that Medtronic USA, Inc. has an agent of record, Corporation Service Company, Inc., at 1703 Laurel Street, Columbia, South Carolina, 29201.

6. The averments in Paragraph 6 of the Complaint are directed at a party other than those answering this Complaint, therefore no response by Medtronic is required.

JURISDICTION AND VENUE

7. Paragraph 7 of the Complaint contains legal conclusions to which no response is required. Paragraph 7 of the Complaint also is directed, in part, at a party other than those answering this Complaint, to which no response by Medtronic is required. To the extent a response is required, Medtronic denies the averments in Paragraph 7. Medtronic further states that neither Medtronic, Inc., nor Medtronic USA, Inc., are proper parties to this action because they are not involved in the design, manufacture, marketing, distribution, testing and/or sale of the diabetes products at issue.

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required.

9. In response to the averments in Paragraph 9 of the Complaint, Medtronic denies that it is liable to Plaintiff in any manner whatsoever, and denies each and every allegation of the Paragraph separately and severally to the extent said allegations imply any wrongdoing by

Medtronic. Medtronic also states the averments in Paragraph 9 contain legal conclusions to which no response is required. Medtronic further states the averments in Paragraph 9 are directed, in part, at a party other than those answering this Complaint, to which no response by Medtronic is required.

10. In response to the averments in Paragraph 10 of the Complaint, Medtronic denies that it is liable to Plaintiff in any manner whatsoever, and denies each and every allegation of the Paragraph separately and severally to the extent said allegations imply any wrongdoing by Medtronic or alleged failure of any Medtronic products. Medtronic also states the averments in Paragraph 10 contain legal conclusions to which no response is required. Medtronic further states the averments in Paragraph 10 are directed, in part, at a party other than those answering this Complaint, to which no response by Medtronic is required.

FACTUAL ALLEGATIONS

11. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 11 of the Complaint.

12. In response to the averments in the first sentence of Paragraph 12 of the Complaint, Medtronic lacks knowledge or information sufficient to form a belief as to Plaintiff's medical condition or treatment plan. Medtronic generally admits that Medtronic MiniMed 630G (MMT-1715) Insulin Pumps hold insulin in a reservoir, and that insulin is delivered to the patient's body through a device called an infusion set. In response to the averments in the second sentence of Paragraph 12, Medtronic lacks knowledge or information sufficient to form a belief as to the period of time in which insulin was delivered to Plaintiff's body. Except as thus stated, Medtronic denies the remaining averments in Paragraph 12.

13. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 13 of the Complaint, and therefore denies the same.

14. Medtronic lacks knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 14 of the Complaint, and therefore denies the same.

15. Medtronic denies the averments in the first sentence of Paragraph 15 of the Complaint. Medtronic specifically denies that the devices Plaintiff alleges were used malfunctioned, or that they were defective in any way. In response to the remaining averments of Paragraph 15 of the Complaint, Medtronic lacks knowledge or information sufficient to form a belief as the truth of the averments, and therefore denies the same.

16. Medtronic denies the averments of Paragraph 16 of the Complaint.

17. In response to the averments in Paragraph 17 of the Complaint, Medtronic admits that Becton Dickinson notified Medtronic in December 2016 that Becton Dickinson had initiated a voluntary recall of the MiniMed Pro-set® Infusion Sets. Medtronic also admits that Medtronic MiniMed, Inc. initiated a voluntary recall of specific lots of MiniMed Pro-set® Infusion Sets on September 10, 2017. Medtronic specifically denies that any Medtronic product allegedly used by Plaintiff malfunctioned, or that any Medtronic product allegedly used by Plaintiff was defective in any way. Medtronic further denies that Plaintiff's alleged injuries were caused by her alleged use of Medtronic products. Except as thus stated, Medtronic denies the remaining averments in Paragraph 17.

In response to the averments in Paragraph 18 of the Complaint, Medtronic admits that Medtronic MiniMed, Inc. issued a voluntary Urgent Field Safety Notification on November 21, 2019, which the FDA later classified as a Class I recall. Except as thus stated, Medtronic denies the remaining averments in Paragraph 18.

THE PRODUCTS

18. In response to the averments in Paragraph 19 of the Complaint, Medtronic admits that Medtronic MiniMed, Inc. is an entity that designed MiniMed 630G (MMT-1715) Insulin

Pumps and one of the components in the MiniMed Pro-set® Infusion Sets—the P-cap—and that Medtronic MiniMed, Inc. marketed and distributed MiniMed 630G (MMT-1715) Insulin Pumps and MiniMed Pro-set® Infusion Sets consistent with their labeling. Medtronic also admits that MiniMed Distribution Corp. was an entity involved in the distribution and sale of MiniMed 630G (MMT-1715) Insulin Pumps and Pro-set® Infusion sets, as well as the marketing of said products consistent with their labeling. Medtronic further states the averments in Paragraph 19 are directed, in part, at a party other than those answering this Complaint, to which no response by Medtronic is required. Except as thus stated, Medtronic denies the remaining averments in Paragraph 19 as they are incomplete, imprecise, and inaccurate. Medtronic further states that neither Medtronic, Inc., nor Medtronic USA, Inc., are proper parties to this action because they are not involved in the design, manufacture, marketing, distribution, testing and/or sale of the diabetes products at issue.

19. In response to the averments in Paragraph 20 of the Complaint, Medtronic generally admits that Medtronic MiniMed Infusion Sets are used in conjunction with an insulin pump. Except as thus stated, Medtronic denies the remaining averments in Paragraph 20 as they are incomplete, imprecise, and inaccurate.

20. Medtronic denies the averments in Paragraph 21 of the Complaint.

THE COMPANIES

21. In response to the averments in Paragraph 22, Medtronic admits that the following is part of its Mission Statement: "To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service." Except as thus stated, Medtronic denies the remaining averments in Paragraph 22 as they are incomplete, imprecise, and inaccurate.

22. In response to the averments in Paragraph 23 of the Complaint, Medtronic admits it received a letter from the Food and Drug Administration ("FDA") on June 1, 2009 ("2009 Warning Letter"). Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied. Medtronic further states that Plaintiff's attempted quotations are inaccurate and/or incomplete. In addition, the FDA confirmed that all of the actions required by this letter were resolved by Medtronic as of March 2011, many years prior to the date Plaintiff's insulin pump was manufactured. The 2009 Warning Letter does not apply to Plaintiff's infusion set or insulin pump. Medtronic denies all remaining averments in Paragraph 23.

23. In response to the averments in Paragraph 24 of the Complaint, Medtronic admits it received a letter from the FDA on June 1, 2009. Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied. Medtronic further states that Plaintiff's attempted quotations are inaccurate and/or incomplete. In addition, the FDA confirmed that all of the actions required by this letter were resolved by Medtronic as of March 2011, many years prior to the date Plaintiff's insulin pump was manufactured. The 2009 Warning Letter does not apply to Plaintiff's infusion set or insulin pump. Except as thus stated, Medtronic denies the remaining averments in Paragraph 24.

24. In response to the averments in Paragraph 25 of the Complaint, Medtronic admits it received a letter from the FDA on June 1, 2009. Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied. In addition, the FDA confirmed that all of the actions required by this letter were resolved by Medtronic as of March 2011, many years prior to the date Plaintiff's insulin pump was manufactured. The 2009 Warning Letter does not apply to Plaintiff's infusion set or insulin pump. Medtronic further

states that Plaintiff's attempted quotations are inaccurate and/or incomplete. Except as thus stated, Medtronic denies the remaining averments in Paragraph 25.

25. In response to the averments in Paragraph 26 of the Complaint, Medtronic admits it received a letter from the FDA on June 1, 2009. Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied. In addition, the FDA confirmed that all of the actions required by this letter were resolved by Medtronic as of March 2011, many years prior to the date Plaintiff's insulin pump was manufactured. The 2009 Warning Letter does not apply to Plaintiff's infusion set or insulin pump. Except as thus stated, Medtronic denies the remaining averments in Paragraph 26.

26. Medtronic denies the averments in Paragraph 27 of the Complaint.

27. Medtronic denies the averments in Paragraph 28 of the Complaint. Medtronic admits only that Medtronic MiniMed, Inc. initiated a voluntary recall of a specific lot of Paradigm Quick-set® Infusion Sets, which the FDA later classified as a Class I recall. Medtronic admits that the recalled Paradigm Quick-set® Infusion Sets were manufactured between December 2007 and June 2009, and do not include the infusion set at issue in this action. Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied.

28. In response to the averments in Paragraph 29 of the Complaint, Medtronic admits only that Medtronic MiniMed, Inc. issued a voluntary Urgent Medical Device Safety Notification on June 7, 2013, which the FDA later classified as a Class I recall. Medtronic further states that Plaintiff's attempted quotations are inaccurate and/or incomplete. Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied.

29. In response to the averments in Paragraph 30 of the Complaint, Medtronic admits only that Medtronic MiniMed, Inc. issued a voluntary Urgent Medical Device Safety Notification on June 7, 2013. Medtronic further states that Plaintiff's attempted quotations are inaccurate and/or incomplete. Plaintiff's characterizations, including but not limited to any purported conclusions or actions of the FDA, are denied.

30. Medtronic denies the averments in Paragraph 31 of the Complaint, and specifically denies Plaintiff's characterization of the Urgent Medical Device Safety Notification issued on June 7, 2013, and the voluntary recall of specific lots of infusion sets on September 7, 2017, as they are incomplete, imprecise, and inaccurate.

31. Medtronic denies the averments in Paragraph 32 of the Complaint.

32. Medtronic denies the averments in Paragraph 33 of the Complaint. Medtronic specifically denies that Plaintiff's devices malfunctioned, or that they were defective in any way.

THE CURRENT RECALL

33. In response to the averments in Paragraph 34 of the Complaint, Medtronic admits only that on September 7, 2017, Medtronic initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets.

34. In response to the averments in Paragraph 35 of the Complaint, Medtronic admits that on September 7, 2017, Medtronic initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. Medtronic further states that Plaintiff's attempted quotations are inaccurate and/or incomplete. Except as thus stated, Medtronic denies the remaining averments in Paragraph 35 as they are incomplete, imprecise, and inaccurate.

35. In response to the averments in Paragraph 36 of the Complaint, Medtronic admits that on September 7, 2017, Medtronic initiated a voluntary recall of certain Medtronic MiniMed

Infusion Sets. Except as thus stated, Medtronic denies the remaining averments in Paragraph 36 as they are incomplete, imprecise, and inaccurate.

36. In response to the averments in Paragraph 37 of the Complaint, Medtronic admits that on September 7, 2017, Medtronic initiated a voluntary recall of certain Medtronic MiniMed Infusion Sets. Medtronic further states that Plaintiff's attempted quotations are inaccurate and/or incomplete. Except as thus stated, Medtronic denies the remaining averments in Paragraph 37 as they are incomplete, imprecise, and inaccurate.

37. In response to the averments in Paragraph 38 of the Complaint, Medtronic admits that Becton Dickinson notified Medtronic in December 2016 that Becton Dickinson had initiated a voluntary recall of the MiniMed Pro-set® Infusion Sets. Medtronic further states that some of the allegations in Paragraph 38 are directed, in part, at a party other than those answering this Complaint, to which no response by Medtronic is required. Except as thus stated, Medtronic denies the remaining averments in Paragraph 38.

38. Medtronic denies the averments in Paragraph 39 of the Complaint.

39. In response to the averments in Paragraph 40 of the Complaint, Medtronic admits that Medtronic MiniMed, Inc., on November 21, 2019, issued an Urgent Field Safety Notification related to specific lots of the MiniMed 630G (MMT-1715) Insulin Pumps, which the FDA later classified as a Class I recall. Except as thus stated, Medtronic denies the remaining averments in Paragraph 40 as they are incomplete, imprecise, and inaccurate.

40. In response to the averments in Paragraph 41 of the Complaint, Medtronic admits that Medtronic MiniMed, Inc. received Plaintiff's MiniMed 630G (MMT-1715) Insulin Pump, which was subsequently tested and passed all functional testing. Medtronic denies the remaining averments in Paragraph 41.

CAUSE OF ACTION
FOR A FIRST CASE OF ACTION – STRICT PRODUCT LIABILITY

41. In response to the averments in Paragraph 42 of the Complaint, Medtronic adopts by reference each and every paragraph stated above and reincorporates as if set forth herein.

42. Paragraph 43 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Medtronic denies the averments in Paragraph 43 and further denies there was or is any "design defect" in any of its products.

43. In response to the first sentence of Paragraph 44 of the Complaint, Medtronic admits that Medtronic MiniMed, Inc. is an entity that designed MiniMed 630G (MMT-1715) Insulin Pumps and one of the components in Medtronic MiniMed Infusion Sets—the P-cap—and that Medtronic MiniMed, Inc. tests, markets, distributes, and sells Medtronic 630G (MMT-1715) Insulin Pumps and Medtronic MiniMed Infusion Sets consistent with their labeling. Medtronic also admits that MiniMed Distribution Corp. is an entity involved in the distribution and sale of MiniMed 630G (MMT-1715) Insulin Pumps and Medtronic MiniMed Infusion Sets, as well as the marketing of said products consistent with their labeling. Medtronic further states that neither Medtronic, Inc., nor Medtronic USA, Inc., are proper parties to this action because they are not involved in the design, manufacture, marketing, distribution, testing and/or sale of the diabetes products at issue. Medtronic further states the averments in Paragraph 44 are directed, in part, at a party other than those answering this Complaint, to which no response by Medtronic is required. Medtronic specifically denies the averments in the second, third, and fourth sentences of Paragraph 44. Except as thus stated, Medtronic denies the remaining averments in Paragraph 44.

44. Medtronic denies the averments in Paragraph 45 of the Complaint.

45. Medtronic denies the averments in Paragraph 46 of the Complaint.

46. Medtronic denies the averments in Paragraph 47 of the Complaint.

47. Paragraph 48 of the Complaint states a legal argument to which no response is required. To the extent a response is required, Medtronic denies the averments in Paragraph 48, including each subpart (a) through (d), of the Complaint. Medtronic further states that it complied at all times with all applicable laws and regulations and further states that it at all times satisfied all applicable legal duties.

48. Medtronic denies the averments in Paragraph 49 of the Complaint.

49. Medtronic denies the averments in Paragraph 50 of the Complaint.

50. Medtronic denies the averments in Paragraph 51 of the Complaint.

51. Medtronic denies the averments in Paragraph 52 of the Complaint.

FOR A SECOND CAUSE OF ACTION – NEGLIGENCE

52. In response to the averments in Paragraph 53 of the Complaint, Medtronic adopts by reference each and every paragraph stated above and reincorporates as if set forth herein.

53. Medtronic denies the averment in Paragraph 54 of the Complaint.

54. Paragraph 55 of the Complaint states a legal argument to which no response is required. To the extent a response is required, Medtronic denies the averments in Paragraph 55, including each subpart (a) through (j), of the Complaint. Medtronic further states that it complied at all times with all applicable laws and regulations and further states that it at all times satisfied all applicable legal duties.

55. Medtronic denies the averments in Paragraph 56 of the Complaint.

56. Medtronic denies the averments in Paragraph 57 of the Complaint.

57. Medtronic denies the averments in Paragraph 58 of the Complaint.

58. Medtronic denies the averments in Paragraph 59 of the Complaint.

59. Paragraph 60 of the Complaint states a legal argument to which no response is required. Medtronic further states the averments in Paragraph 60 are directed, in part, at a party

other than those answering this Complaint, to which no response by Medtronic is required. To the extent a response is required, Medtronic denies the averments in Paragraph 60.

60. Medtronic denies the averments in Paragraph 61 of the Complaint.

FOR A THIRD CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

61. In response to the averments in Paragraph 62 of the Complaint, Medtronic adopts by reference each and every paragraph stated above and reincorporates as if set forth herein.

62. Paragraph 63 of the Complaint states a legal argument to which no response is required. To the extent a response is required, Medtronic denies the averments in Paragraph 63. Medtronic further states that it complied at all times with all applicable laws and regulations.

63. Medtronic denies the averments in Paragraph 64 of the Complaint. Medtronic further states that it complied at all times with all applicable laws and regulations.

64. Medtronic denies the averments in Paragraph 65 of the Complaint.

65. Medtronic denies the averments in Paragraph 66 of the Complaint.

66. Medtronic denies the averments in Paragraph 67 of the Complaint.

FOR A FOURTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY

67. In response to the averments in Paragraph 68 of the Complaint, Medtronic adopts by reference each and every paragraph stated and reincorporates as if set forth herein.

68. Medtronic denies the averments in Paragraph 69 of the Complaint.

69. Medtronic denies the averments in Paragraph 70 of the Complaint.

70. Medtronic denies the averments in Paragraph 71 of the Complaint.

71. Medtronic denies the averments in Paragraph 72 of the Complaint.

DAMAGES AS TO ALL CAUSES OF ACTION

72. Medtronic denies the averments in the first two sentences of Paragraph 73 of the Complaint. In response to the third sentence in Paragraph 73, Medtronic states that it is a legal

argument to which no response is required. To the extent a response is required, Medtronic denies the averments in Paragraph 73, including each subpart (a) through (h), of the Complaint. Medtronic specifically denies that it is liable to Plaintiff in any manner whatsoever or that its products were defective.

73. Paragraph 74 of the Complaint contains no averments against Medtronic and, therefore, requires no response. To the extent a response is required, Medtronic denies the averments in Paragraph 74. Medtronic specifically denies that it is liable to Plaintiff in any manner whatsoever or that its products were defective.

74. Medtronic denies the averments in Paragraph 75 of the Complaint.

75. Medtronic denies the averments in Paragraph 76 of the Complaint. Medtronic specifically denies that it is liable to Plaintiff in any manner whatsoever, and denies each and every statement in this section separately and severally to the extent said statement implied any wrongful conduct by Medtronic.

Answering the unnumbered "Wherefore" Paragraph following Paragraph 76 of the Complaint, Medtronic denies that it is liable to Plaintiff in any manner whatsoever, and denies each and every allegation of the Paragraph separately and severally to the extent said allegations imply any wrongdoing by Medtronic. Medtronic further denies that Plaintiff is entitled to any of the relief requested in the "Wherefore" Paragraph, including but not limited to subparts (1) through (4).

AFFIRMATIVE DEFENSES

Without assuming any burden it would not otherwise bear, Medtronic assert the following affirmative defenses or matters of avoidance:

1. Plaintiff's Complaint and each and every purported cause of action therein fails to state a claim upon which relief can be granted, and the Complaint should therefore be dismissed in whole or in part.

2. Plaintiff's claims against Medtronic, Inc. and Medtronic USA, Inc. are barred because they are not proper parties to this action involving devices designed, licensed, manufactured, marketed, distributed, and sold by other Defendants and/or third parties.

3. Plaintiff's claims are or may be, as a matter of law, preempted or impliedly preempted, in whole or in part, by federal law, specifically 21 U.S.C. §§ 360k(a) and 337(a), as stated in the United States Supreme Court's decisions in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

4. Plaintiff's claims may be preempted, in whole or in part, by federal law, including but not limited to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394.

5. Plaintiff's claims may be barred, in whole or in part, because the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394, do not provide for a private right of action.

6. Plaintiff's claims are barred, in whole or in part, because there was no defect in the subject products at the time they left the manufacturer, seller, and/or distributor's possession. The products were not unreasonably dangerous or defective, were suitable for the purpose for which they were intended, and were properly designed, manufactured, tested, inspected, and distributed with adequate and sufficient warnings at the time they left Medtronic's custody and control.

7. Any damages that Plaintiff may have sustained were, or may have been, proximately caused by the negligence and fault of Plaintiff, and/or by the actions or inactions of

third persons or parties or entities not reasonably expected by Medtronic and not named herein over whom Medtronic exercised no authority or control.

8. Any alleged product defect, negligence, or breach of warranty was not the proximate cause of the injuries alleged by Plaintiff.

9. At all relevant times, the products at issue were accompanied by proper directions for use, pursuant to generally recognized prevailing standards in existence at the time. The warnings and instructions on the products were proper and not the proximate cause of any injury alleged by Plaintiff.

10. Any injuries or damages that Plaintiff may have sustained—although Medtronic denies any such injury or damage—were the result of Plaintiff's knowing and voluntary assumption of the medical risks associated with the use of the devices described in the Complaint. Therefore, Plaintiff's damages, if any, are barred, in whole or in part, by the principles of assumption of risk and informed consent.

11. Any danger or risk associated with the use of the device manufactured by Medtronic and at issue in this lawsuit was readily apparent, open or obvious, or was adequately warned against.

12. The injuries alleged by Plaintiff, without admitting such occurred, were or may have been caused, in whole or in part, by the misuse of the products not reasonably foreseeable to Medtronic, or because the use was contrary to the instructions provided with the products.

13. Plaintiff's claims are barred, in whole or in part, by Plaintiff's own comparative and/or contributory negligence insofar as she committed acts or omissions that have proximately caused the damages alleged in the Complaint.

14. Plaintiff's claims are barred, in whole or in part, because the methods, standards, and techniques utilized in the preparation, design, manufacture, and marketing of the products

were and are in conformity with the generally recognized state of medical knowledge, common and accepted procedure in the medical field, and state of the art at the time.

15. Medtronic avers that the invitation for a court or jury to impose liability on Medtronic for a product design which was in conformance with standards set by the United States government would deny Medtronic due process of law in violation of the Fourteenth Amendment to the United States Constitution.

16. Plaintiff's claims are or may be barred, in whole or in part, by the learned intermediary doctrine.

17. Plaintiff's claims are or may be barred, in whole or in part, by the doctrines of estoppel, collateral estoppel, laches, and/or the doctrines of accord, release, satisfaction, and waiver.

18. Plaintiff's claims are or may be barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose, including but not limited to Sections 15-3-530, 15-3-535, 15-3-545, and 36-2-725 of the South Carolina Code of Laws.

19. Plaintiff's claims are barred, in whole or in part, because at all times relevant the products and marketing of the products complied with all applicable laws and regulations to which the products were in any respect subject, including those of the Food and Drug Administration.

20. Plaintiff's claims are barred, in whole or in part, under Comment K of Section 402A of the Restatement (Second) of Torts (1965)—as codified under Section 15-73-30 of the South Carolina Code of Laws—and the Restatement (Third) of Torts: Product Liability §§ 2, 4, 6 and applicable case law.

21. Plaintiff's claims are barred, in whole or in part, by the principles set forth in Comment N to Section 388 of the Restatement (Second) of Torts (1965).

22. If it is established that Medtronic is in any manner legally responsible for any of the damages Plaintiff claims, which Medtronic wholly denies, those damages were proximately contributed to and caused by other defendants, persons, or entities not yet parties to this action, and as a result, Medtronic is entitled to equitable indemnity/contribution from each of said other defendants, persons, and entities in an amount in direct proportion to the culpable conduct of said other defendants, persons, or entities, pursuant to Sections 15-38-15 and 15-38-20 of the South Carolina Code of Laws.

23. Medtronic has been prejudiced in its defense to the extent evidence relevant to this case has been damaged, changed, repaired, serviced, destroyed, spoliated, or altered by others, before Medtronic had an opportunity to begin its investigation.

24. If any defect existed in the products at the time of the incident which caused or contributed to the injuries and/or damages alleged, the condition of the products were not the same as when they left the custody and control of Medtronic, substantial changes, misuse or alterations having been made thereto, which changes, misuse, and/or alterations were the proximate cause of any such defective condition or conditions and resulting damages, thus barring or reducing proportionately all claims against Medtronic.

25. The products' designs were reasonably safe as measured by the risk-utility analysis set forth in the Restatement (Third) of Torts: Products Liability.

26. Plaintiff's claims are or may be barred, in whole or in part, by Sections 15-73-10 and/or 15-73-20 of the South Carolina Code of Laws, and other applicable South Carolina law.

27. Medtronic denies the existence of any implied warranty or breach of warranty. Medtronic further avers that it did not receive any timely notice of the alleged breach of warranty, that Plaintiff did not reasonably rely on any purported warranty issued by Medtronic,

and that Medtronic was not the "seller" of the subject devices as that term is used in Section 15-73-10 of the South Carolina Code of Laws.

28. Plaintiff's warranty-based claims are or may be barred, in whole or in part, because Plaintiff did not reasonably rely on any representation or omission by Medtronic.

29. Plaintiff's warranty-based claims are barred and/or limited by any and all express conditions or disclaimers given by Medtronic.

30. Plaintiff's warranty-based claims are or may be barred, in whole or in part, because Plaintiff is not in privity with Medtronic.

31. Plaintiff's claims are barred in whole or in part because punitive damages or other exemplary damages are not recoverable for the causes of action set forth in Plaintiff's Complaint, or in the alternative, the allegations of each cause of action set forth in Plaintiff's Complaint are legally insufficient to support a claim for punitive or exemplary damages as to each cause of action. Medtronic denies it is guilty of conduct for which punitive damages could or should be awarded, and denies that Plaintiff has produced clear and convincing evidence sufficient to support or sustain the imposition of punitive damages against Medtronic under Section 15-32-520 of the South Carolina Code of Laws.

32. Plaintiff's claim for punitive damages is barred by the Due Process Clauses of the United States Constitution (Amendment V and Amendment XIV, § 1), and the Constitution of the State of South Carolina (Article I, § 3) to the extent that the law of this State governing punitive damages, as written or applied, provides inadequate procedural protections against arbitrary or erroneous awards of such damages; fails to provide fair notice that such punitive awards would be awarded; fails to impose a close relationship between appropriate civil fines and penalties established by the legislature or administrative bodies; discriminates against non-resident corporate defendants; imposes penalties for extra-territorial conducts; permits the

introduction of a defendant's financial condition with respect to the quantum of punitive damages which then invites a jury to award an arbitrary amount based upon the defendant's status as an industrial enterprise; constitutes an excessive fine under Amendment VIII to the United States Constitution; fails to adhere to the Due Process limitations of "reprehensibility factors"; fails to require a close nexus between a defendant's conduct and Plaintiff's alleged harm; or fails to prohibit "double counting" by the inclusion of compensatory damages in the quantum of punitive damages.

33. Plaintiff's claims may be barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitation of awards, caps on recovery, and setoffs, including but not limited to the limitations on punitive damages set forth in Section 15-32-530 of the South Carolina Code of Laws.

34. Medtronic reserves the right to assert any additional defenses and matters in avoidance as may be appropriate upon the facts and issues disclosed during the course of additional investigation and discovery.

Except as expressly admitted above, all allegations in Plaintiff's Complaint are denied, and Medtronic further denies that Plaintiff is entitled to the relief requested in the Complaint.

DEMAND FOR BIFURCATED TRIAL

If Plaintiff is permitted to proceed to trial upon any claims for punitive or exemplary damages, such claims, if any, should be bifurcated from the remaining issues.

JURY DEMAND

WHEREFORE, having fully answered and defended, Medtronic requests a trial by jury on all issues and causes of action so triable in this case and prays for judgment as follows:

A. That Plaintiff take nothing by her Complaint;

B. That judgement be entered for Medtronic and against Plaintiff on each and every

claim set forth in Plaintiff's Complaint;

C. That Medtronic recover its costs of suit; and

D. For such other and further relief as the Court deems just and proper.

Respectfully submitted,

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April 6, 2020
Greenville, South Carolina

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing was served by the Court's ECF system upon the following counsel of record on April 6, 2020:

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